UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/956,925	09/21/2001	Hideaki Yagi	Q66253	2471

7590 06/04/2003

SUGHRUE MION ZINN MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, NW
Washington, DC 20037-3213

EXAMINER
RADEMACHER, MARK A

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No.	Applicant(s)	
	09/956,925	YAGI ET AL.	
	Examiner	Art Unit	
	Mark Rademacher	3761	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-28 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The use of the trademark SIROOCO® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

3. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

4. The disclosure is objected to because the applicant has used sixth paragraph, means-plus-function language to define features of the applicants' invention. Accordingly, the examiner requires the applicants to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicants to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see MPEP 2181 (Rev. 1, Feb.2000)).

Appropriate correction is required.

Claim Objections

5. Claims 2, 3, 9 and 10 objected to for the following reasons. In claims 2 and 9 the applicants recites "a continuous base flow rate representing a flow rate at which the oxygen enriching apparatus can supply the oxygen-enriched gas continuously". The nature of a flow rate that "represents" another flow rate is not clear form the specification, the claims or the prior art. Accordingly, the metes and bounds of the claim as presently drafted are not ascertainable. Similarly, the recitation in claims 3 and 10 of "which third flow rate represents a flow rate at which the oxygen enriching apparatus can supply the oxygen-enriched gas continuously" is indefinite.

6. In order to increase the clarity of the claims the examiner suggests that the applicants correct the above clauses to read "a continuous base flow rate that is the flow rate at which the oxygen apparatus can supply oxygen-enriched gas continuously", or "which third flow rate that is the flow rate at which the oxygen enriching apparatus can supply the oxygen-enriched gas continuously".

7. In addition, claims 2, 3, 5, 6, 9-14, 16, 18, 20, 22, 23, 24, 26 and 28 are objected to because the applicants has evoked sixth paragraph, means-plus-function language to define features of the applicants' invention. Therefore the examiner objects to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required. The applicants are invited to review the claims and make like corrections and clarifications where necessary.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 3-6, 10 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

10. In claim 3, the applicants recite "a third flow rate". However, the applicants have not recited first and second flow rates in the claim. As a result it is unclear which flow rate(s) is/are being referred to in the claim.

11. The metes and bounds of claim 10 are not ascertainable from the claims, the specification or the prior art. First, because the applicants recites "a continuous base flow rate" in claim 10 after previously defining "a continuous base flow rate" in claim 9, it is unclear whether the applicants is referring to more than one continuous base flow rate or referring to the same continuous base flow rate in both instances. In addition, the applicants refer to "a flow rate at which the oxygen enriching apparatus can supply the oxygen-enriched gas continuously". It is unclear whether the applicants are referring to the continuous base flow rate or some other flow rate that has the same characteristics.

12. Also in claim 10, the applicants recites "a third flow rate equal to or less than a continuous base flow rate" and that the "third flow rate represents a flow rate at which the oxygen enriching apparatus can supply the oxygen-enriched gas continuously". The metes and bounds of the claim are not ascertainable because it is unclear how the third flow rate can both "represent" a flow rate at which the oxygen enriching apparatus can supply the oxygen-enriched

gas continuously while at the same time be defined as something different than what appears to be that same continuous flow rate, i.e., something "equal to or less than" the flow rate at which the oxygen enriching apparatus can supply the oxygen-enriched gas continuously, which was earlier defined in claim 9 as the continuous base flow rate. Depending claim 24 incorporates the indefiniteness of claim 10.

13. Claim 4 recites the limitation "the breath detection port" in line 4. There is insufficient antecedent basis for this limitation in the claim. As a result it is unclear what breath detection port to which the applicants are referring in claim 4. Claims 5 and 6 incorporate the indefiniteness of claim 4.

14. The applicants are invited to review the claims and make like corrections and clarifications where necessary.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 4-8, 15, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent no. 5,720,276 to *Kobatake et al.*

17. *Kobatake et al* disclose an oxygen-enriching device that supplies oxygen-enriched gas to user synchronously with the exhalation and inhalation of the user. The apparatus includes an oxygen outlet in the form of outlet port (12p) that supplies oxygen-enriched gas to the user.

18. The device disclosed includes a controller (22) and pressure sensor (34). The pressure sensor (34) is disposed on a flow passage (18) that reaches a breath detection port in the nasal cannulae (36). During an intermittent mode the controller (22) interacts with the sensor (34) and a valve (32) to control the flow of oxygen. The state of inhalation or expiration is detected based on a signal from the sensor (34). See, e.g., column 7, line 7-29.

19. The controller disclosed for performing the operations recited in claim 1 includes a recording medium in the form of RAM (22a) and/or ROM (22b).

20. The main passage (18a) of the device includes a control member that adjusts the opening in the main passage (18a) in the form of an adjustable flow reducer (24). A bypass flow passage (18b) bypasses the control member (24). The bypass flow passage further includes flow rate adjuster (26). FIG 1.

21. The oxygen enriching device disclosed by *Kobatake et al* further includes a tank (12h) in an oxygen-enriched-gas supply passage and downstream of an oxygen enriching section that includes a compressor (12a) and nitrogen absorber (12f). FIGS 1 and 2.

22. The apparatus disclosed by *Kobatake et al* includes a switch (40) that allows the device to provide either a continuous flow of oxygen to a patient or a pulsed flow wherein the pulsed flow is delivered during a time that corresponds to 25-40% of the breath cycle, namely one-third of the mean time for the respiration. See the third full paragraph in column 7.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 2, 3, 9-14, 16, 23, 24, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 5,720,276 to *Kobatake et al* in view of US patent no. 6,123,074 to *Hete et al.*

25. *Kobatake et al* disclose all of the features recited in the above claims except that the means for controlling the oxygen enriched gas does so at a first flow rate during the inhalation period of each breathing cycle and at a second flow rate during the exhalation period of each breathing cycle during breath synchronization.

26. In the context of a positive pressure ventilator, *Hete et al* teach means for providing oxygen-enriched gas at a flow rate above the average continuous flow rate during inhalation and decreasing the flow of gas below the average flow rate to the patient during exhalation. See column 8, line 66 through column 9, line 27.

27. At the time of invention it would have been obvious to one with ordinary skill to modify the oxygen enriching apparatus disclosed by *Kobatake et al* to configure the disclosed means for controlling gas flow to the user to provide oxygen-enriched gas at first, second and third flow rates corresponding to the IPAP, EPAP and average continuous flow rates taught by *Hete et al.*

28. One would have been motivated to make such a modification in order to make the user more comfortable, which is a well-known benefit of bi-level positive pressure ventilators. See, e.g., column 4, lines 17-21 of US patent no. 5,148,802 to *Sanders et al.*

Claims 17, 19 and 21

29. Claims 17, 19 and 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 5,720,276 to *Kobatake et al* in view of US patent o. 6,237,594 to *Davenport.*

30. *Kobatake et al* disclose all of the features recited in claim 17 except a plurality of tanks in series in the oxygen-enriched-gas supply passage.

31. However, the use of a plurality of tanks in an oxygen supply passage was known at the time of invention. For example, *Davenport* discloses an oxygen supply device wherein a number of tanks (i.e., boluses 46 and 50) are used to allow the device to deliver a broad range of flow to the patient without negatively impacting the performance of the valves and sensors. A check valve (62) is provided between the boluses. See column 5, lines 60-68.

32. Accordingly, it would have been obvious to one with ordinary skill in the art to modify the *Kobatake et al* device to include additional tanks in the gas supply line as taught by *Davenport* in order to allow the apparatus to deliver gas over a wide range of flow rates without negatively impacting the performance of the valves and sensors.

33. Regarding the size of the tanks recited in claim 19, although the size of the tanks/boluses is not expressly disclosed, it is well known that the greater the size of the buffer tanks, the greater the efficiency in delivering gas to a patient over a wide range of flow rates. See, e.g., the discussion of Table 4 of US patent no. 4,681,099 to *Sato et al.* Accordingly, because the applicants does not disclose that a tank sized at 500ml or more solves a problem or provides an advantage not addressed in the prior art, it would have been an obvious design choice to provide tanks having at least 500 ml capacity in order to efficiently provide the range of desired flow rates.

Claims 18, 20 and 22

34. Claims 18, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kobatake et al* in view of *Hete et al* as applied to claim 9 above, and further in view of US patent no. 6,237,594 to *Davenport*.

35. *Kobatake et al* in view of *Hete et al* teach the invention recited in claims 18, 20 and 22 except for the use of a plurality of tanks in the gas supplying line

36. However, as explained above, the use of a plurality of tanks in an oxygen supply passage was known at the time of invention. For example, *Davenport* discloses an oxygen supply device wherein a number of tanks (i.e., boluses 46 and 50) are used to allow the device to deliver a broad range of flow to the patient without negatively impacting the performance of the valves and sensors. A check valve (62) is provided between the boluses. See column 5, lines 60-68 of *Davenport*.

37. Accordingly, it would have been obvious to one with ordinary skill in the art to further modify the *Kobatake et al* device to include additional tanks in the gas supply line as taught by *Davenport* in order to allow the apparatus to deliver gas over a wide range of flow rates without negatively impacting the performance of the valves and sensors.

38. Regarding the size of the tanks recited in claim 18, although the size of the tanks/boluses is not expressly disclosed, it is well known that the greater the size of the buffer tanks, the greater the efficiency in delivering gas to a patient over a wide range of flow rates. See, e.g., the discussion of Table 4 of US patent no. 4,681,099 to *Sato et al*. Accordingly, because the applicants does not disclose that tanks sized to 500ml or more solves a problem or provides an advantage not addressed in the prior art, it would have been an obvious design choice to provide

tanks having at least 500 ml capacity in order to efficiently provide the range of desired flow rates.

Additional Pertinent Prior Art

39. The following prior art s considered pertinent to the applicants' disclosure: US patent no. 5,697,364 to *Chua et al.*

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR
May 30, 2003

GLENN K. DAWSON
PRIMARY EXAMINER

NOTICE – CHANGE OF ADDRESS FOR THE COMMISSIONER FOR PATENTS

As of May 1st, 2003 the correspondence address for the Director of the USPTO and the Commissioner for Patents will be:

PO Box 1450
Alexandria, VA 22313-1450

See, Federal Register, Vol. 68, No. 57, March 25, 2003.